

## 510(k) Summary of Safety and Effectiveness

*This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.*

### Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

### Submitter name, Address, and Contact

Lin-Zhi International, Inc.  
2391 Zanker Road, Suite 340  
San Jose, CA 95131  
Phone: (408) 944-0360  
Fax: (408) 944-0359

Contact: Chiu Chin Chang, Ph.D.  
VP, R&D

### Device Name and Classification

- (a) Classification Name: Calibrators, Drug Specific;  
Class II, DLJ (91 Toxicology), 21 CFR 862.3200  
Common/Usual Name: Phencyclidine Calibrators,  
Opiate Calibrators,  
Cocaine Calibrators, and  
Amphetamine Calibrators  
Proprietary Name: None
- (b) Classification Name: Single (Specified) Analyte Controls (Assayed and Unassayed);  
Class I, LAS (91 Toxicology), 21 CFR 862.3280  
Common/Usual Name: Phencyclidine Controls,  
Opiate Controls,  
Cocaine Controls, and  
Amphetamines Controls  
Proprietary Name: None

### Legally Marketed Predicate Device(s)

Lin-Zhi International, Inc.' Single Analyte Urine Drugs of Abuse Calibrators and Controls are substantially equivalent to the Drugs of Abuse Urine Calibrators and Controls (Diagnostic Reagents, Inc., now Microgenics Corporation), cleared under premarket notification K983159.

## Device Description

All of the Single Analyte Urine DAU Calibrators and Controls are human urine-based liquid, and ready to use. These Calibrators and Controls do not have any especially unique technical characteristics. When applicable, they contain known concentration of a specific drug analyte.

The Negative DAU Calibrator is a processed, drug-free human urine matrix. The Low, Cutoff, Intermediate, and High Calibrators, as well as the 2 levels of Controls are prepared by spiking known concentrations of drug analyte into the Negative DAU Calibrator matrix. The various concentrations of each drug analyte in their corresponding calibrators and controls are summarized as follows:

	<b>Phencyclidine EIA</b>	<b>Opiate EIA</b>	<b>Cocaine Metabolite EIA</b>	<b>Amphetamines EIA</b>
<b>Reference Material</b>	Phencyclidine	Morphine	Benzoyllecgonine	<i>d</i> -Methamphetamine
<b>Low Calibrator</b>	12.5 ng/mL	150 ng/mL	150 ng/mL	500 ng/mL
<b>Cutoff Calibrator</b>	25 ng/mL	300 ng/mL	300 ng/mL	1000 ng/mL
<b>Intermediate Calibrator</b>	50 ng/mL	600 ng/mL	1000 ng/mL	1500 ng/mL
<b>High Calibrator</b>	100 ng/mL	1000 ng/mL	3000 ng/mL	2000 ng/mL
<b>Control Level 1</b>	18 ng/mL	225 ng/mL	225 ng/mL	750 ng/mL
<b>Control Level 2</b>	32 ng/mL	375 ng/mL	375 ng/mL	1250 ng/mL

The nominal concentrations of the analyte in the calibrators and controls are determined and confirmed by GC/MS.

## Intended Use

The Single Analyte Urine Drugs of Abuse (DAU) Calibrators are intended for in vitro diagnostic use for the calibration of their respective DAU enzyme immunoassays to detect phencyclidine, opiates, cocaine metabolite, or amphetamines in human urine.

The Single Analyte Urine Drugs of Abuse (DAU) Controls are intended for in vitro diagnostic use for the validation of their respective DAU enzyme immunoassays to detect phencyclidine, opiates, cocaine metabolite, or amphetamines in human urine.

## Comparison to Predicate Device

LZI's Single Analyte Urine DAU Calibrators and Controls are similar in intended use, matrix, and performance to the DRI's Drugs of Abuse Urine Calibrators and Controls.

### Similarities:

- Both are for the calibration and validation of DAU enzyme immunoassays to detect the same commonly abused drug analytes (phencyclidine, opiates, cocaine metabolite, or amphetamines) in human urine.

- The cutoff concentration for each analyte is the same per recommendations of The Substance Abuse and Mental Health Services Administration (SAMHSA).
- Both use 2 levels of Controls, and the concentrations are set at equal to or approximately  $\pm 25\%$  of the cutoff concentration for each analyte according to the SAMHSA guideline.
- The nominal concentrations of the analyte in the calibrators and controls are determined and confirmed by GC/MS.
- Both are urine-based liquids.
- Storage condition is the same, at 2°C to 8°C.
- Performance characteristics on precision, accuracy and stability are similar.

Differences:

<b>Characteristics</b>	<b>DRI's DAU Urine Calibrators and Controls</b>	<b>LZI's Single Analyte Urine DAU Calibrators and Controls</b>
<b>No. of Analytes in each Calibrator or Control</b>	All 4 drugs in each Calibrator or Control	Single drug only in each Calibrator or Control.
<b>No. of Calibrators</b>	3 levels* including the Negative Calibrator.	5 levels including the Negative Calibrator
<b>Nomenclature/Labeling of Calibrators</b>	Negative, Low (= Cutoff), and High	Negative, Low, Cutoff, Intermediate, and High
<b>Concentration of Analyte(s)</b>	Phencyclidine Controls: 20 and 35 ng/mL Cocaine High Calibrator: 1000 ng/mL	Phencyclidine Controls: 18 and 32 ng/mL, Cocaine High Calibrator: 3000 ng/mL

\*Additional calibrators are now available. Currently 5 levels of calibrators (Cal 0, 1, 2, 3, and 4) are available from DRI/Microgenics Corp. (under "Multi-drug Urine Calibrators and Controls" product name).

## Conclusion

The information provided in the premarket notification demonstrates that the LZI's Single Analyte Urine Drugs of Abuse Calibrators and Controls are substantially equivalent to previously approved predicate devices, notably the DRI's DAU Urine Calibrators and Controls, and safe and effective for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
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San Jose, CA 95131

APR 03 2002

Re: k020769  
Trade/Device Name: Single Analyte Urine Drugs of Abuse Calibrators and Controls  
Regulation Number: 21 CFR 862.3280; 21 CFR 862.3200  
Regulation Name: Clinical toxicology control material; Clinical toxicology calibrator  
Regulatory Class: Class I; Class II  
Product Code: LAS; DLJ  
Dated: February 28, 2002  
Received: March 7, 2002

Dear Dr, Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

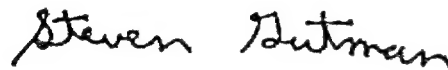
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory-Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### Indications for Use Statement

**Device Name: Single Analyte Urine Drugs of Abuse Calibrators and Controls**

The Single Analyte Urine Drugs of Abuse (DAU) Controls are intended for in vitro diagnostic use for the validation of their respective DAU enzyme immunoassays to detect phencyclidine, opiates, cocaine metabolite, or amphetamines in human urine.

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

## Over-The-Counter Use

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